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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,720	08/25/2003	Christine Markert-Hahn	810102.401	3616

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EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
10/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,720	MARKERT-HAHN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/10 has been entered.

The response filed 2/12/10 to the Office action has been entered. Claims 1 and 3-11 are pending.

Response to Arguments

2. Applicant's arguments filed 2/12/10 have been fully considered but they are not persuasive with the reasons as set forth below.

Regarding the rejection of claims 1 and 3-5 under 35 U.S.C. 103 over Herman et al. (5,786146, issued July 28, 1998) in view of Gerdes et al. (6,291,166, issued Sep. 18, 2001), the response argues that Gerdes et al. do not disclose the use of the solid phase in bisulfite modification, while Gerdes et al. disclose the use of solid phase in purification of DNA or RNA, solid phase manipulation and analysis including enzyme recognition, hybridization and amplification. Although Gerdes et al. do not explicitly disclose the use of the solid phase in bisulfite modification, Gerdes et al. disclose solid phase manipulation and analysis including enzyme recognition, hybridization and amplification, which suggests that other desirable chemical reactions would also be successful on the solid support.

The response further argues that if a single stranded DNA is immobilized, it would be expected to interact with the support in a manner similar to base pairing, and bisulfite ions would not be expected to be able to interact with cytosine in the DNA. However, the instant claims do not require any particular conditions for either immobilization or sulfite treatment. It was conventional in the art to use support-immobilization capture probes in sandwich hybridization, meaning that immobilized single stranded DNA was well known in the art to be accessible to other single stranded DNA, and thus accessibility would have been expected with other molecules as well, such as sulfite. Moreover, Gerdes et al. disclose isothermal amplification using bound DNA which requires a single stranded target nucleic acid (see column 10, lines 5-9). This inherently teaches the immobilized DNA is not "base paired" with the support and is accessible for chemical reactions. Based upon the analysis above, one of ordinary skill in the art would have thought it more likely than not that sulfite treatment would have been successful using immobilized DNA.

Regarding the rejection of claims 6-11 the rejection over Herman et al. (5,786146, issued July 28, 1998) in view of Gerdes et al. (6,291,166, issued Sep. 18, 2001) as applied to claims 1 and 3-5 above, and further in view of Weindel et al. (WO 01/37291, issued May 21, 2001), the response argues the same issues as set forth above. For the same reasons, the rejection is maintained.

3. The Declaration of Matthias Ballhause under 37 CFR 1.132 filed 2/12/10 is insufficient to overcome the rejection of claims 1 and 3-11 based upon the rejection under 35 U.S.C. 103 over Herman et al. (5,786146, issued July 28, 1998) in view of Gerdes et al. (6,291,166, issued

Sep. 18, 2001) and Weindel et al. (WO 01/37291, issued May 21, 2001) as set forth in the last Office action.

The Declaration argues that it would not have been expected that a denatured nucleic acid bound to a solid support such as a magnetic glass particle or silica surface would be successfully subjected to bisulfite treatment because bisulfite ions react with pyrimidine bases like cytosine which would not be accessible if involved in base-pairing-like interactions with a solid support. However, the instant claims do not require any particular manner of binding a solid support, nor any particular conditions for carrying out bisulfite treatment.

Although the Declaration alleges that a successful bisulfite reaction with a single stranded DNA bound to a solid phase was a surprising and unexpected finding, there is no evidence of record to support this. As noted above, while it is argued that immobilized single stranded-DNA was thought in the art to interact with a solid phase in a base-pairing-like way and thus not be available for chemical interactions, it was clearly conventional in the art to subject immobilized DNA to hybridization, meaning said DNA was accessible to interaction with other molecules.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added language "single stranded" has no support in the specification. It constitutes new matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al. (5,786146, issued July 28, 1998) in view of Gerdes et al. (6,291,166, issued Sep. 18, 2001).

Herman et al. disclose a methylation specific PCR (See the Abstract). The method involves the step of conversion cytosine to uracil. Bisulfite modification includes denaturing DNA by NaOH, incubating the nucleic acid in the presence of sulfite ions, binding the deaminated nucleic acid to a solid phase. Modified DNA was purified. Modification was completed by NaOH treatment, followed by ethanol precipitation (See column11, lines 15-28).

Herman et al. do not disclose that a nucleic acid is bound to a solid phase and then the nucleic acid is deaminated.

Gerdes et al. disclose a method of using solid phases to irreversibly capture RNA or DNA and teaches true, direct solid phase manipulation and analyses including enzyme recognition, hybridization and amplification (see column 3, lines 39-49, column 4, and lines 45-48).

One of ordinary skill in the art would have been motivated to apply a solid phase bound DNA as taught by Gerdes et al. in the method of Herman et al. because as taught by Gerdes et al. a solid phase bound nucleic acid can be directly and conveniently manipulated (see column 4, lines 45-46) and can be applied in various ways for example treating/manipulating/analyzing/amplifying nucleic acids (see column 4, lines 43-48). It would have been prima facie obvious to use solid phase bound nucleic acid as recited in the instant claims.

7. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al. (5,786146, issued July 28, 1998) in view of Gerdes et al. (6,291,166, issued Sep. 18, 2001) as applied to claims 1 and 3-5 above, and further in view of Weindel et al. (WO 01/37291, issued May 21, 2001).

The teachings of Herman et al. and Gerdes et al. are set forth in section 6 above.

Herman et al. do not disclose that the solid phase comprises magnetic glass particle, the magnetic particle has diameter between 0.5 and 5um, and the magnetic glass particle is manufactured by the sol-gel method.

Weindel et al. disclose that magnetic glass particles can be used in nucleic acid purification (See the abstract). The magnetic glass particle is a solid dispersion of small magnetic

core in glass (See pg. 4, lines 9-11). The diameter of the particle is between 5 and 500nm (See pg. 4, lines 21-23 and pg. 5, lines 13-23). The magnetic glass particle is used in nucleic acid purification from a sample containing cells. The advantage of this is its potential simplicity and high sensitivity (See pg. 17, lines 1-7). Weindel et al. also disclose a method of making the magnetic glass particles by the sol-gel method and spray-drying as recited in instant claim 11 (See pg. 9, lines 13-37, pg. 21 and fig. 1). The magnetic glass particle is also used in nucleic acid amplification and hybridization assay (See pg.1).

One of ordinary skill in the art would have been motivated to apply the magnetic glass particle of Weindel et al. in the method of Herman et al. as a solid support for converting cytosine bases to uracil bases because of the advantage of using the magnetic glass particle (See pg. 17, lines 1-17). It would have been prima facie obvious to apply a magnetic glass particle for the conversion of cytosine bases to uracil bases in a nucleic acid.

Summary

8. No claims are free of the prior art.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Joyce Tung/
Examiner, Art Unit 1637
October 19, 2010